

Claims 1-33 and 35-38 teach non-aqueous single phase biocompatible viscous vehicles, formulations comprising such vehicles, methods for preparing said vehicle and formulations, and methods for treating a subject utilizing said formulations.

*Knepp et al.* teaches a vehicle selected from the group consisting of perhalohydrocarbons, unsubstituted saturated hydrocarbons, halogenated hydrocarbons, esters of unsubstituted saturated or halogenated hydrocarbons and ethers of unsubstituted saturated or halogenated hydrocarbons.

*Roorda et al.* teaches (column 4, lines 1-2) aqueous solutions containing a viscosity-elevating solute.

*Nuwayser* teaches a transdermal drug delivery system in which the drug microparticles are polymer coated and then suspended in a viscous liquid base material or vehicle (column 7, lines 14-16). The liquid base material of *Nuwayser* is taught in column 9, lines 8-20 wherein it is taught that the liquid base material may comprise "a water solution placed in a gel-like form".

To make out a *prima facie* case for obviousness there must be a suggestion or motivation to modify the reference or combine references; there must be a reasonable expectation of success; and the reference(s) must teach or suggest all of the claim limitations.

Applicants respectfully point out that the Examiner has not made out a *prima facie* case for obviousness.

There is no suggestion or motivation in any of the three references cited by the Examiner to modify them or combine them. In fact, in *Roorda et al.* (column 2, lines 15-21) it is stated that particles of biologically effective agent microencapsulated in a diffusion-limiting shell are difficult to manufacture and it is difficult to control the release rate of the agent from the shell. This teaches away from the polymer coated active agent of *Nuwayser*. *Knepp, et al.* does not discuss microencapsulation of the active agent.

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There is no reasonable expectation that combining any or all of the three references will result in success. *Roorda et al.* and *Nuwayser* teach away from each other in relation to coating an active agent prior to formulating it in a vehicle.

None of the three references, nor a combination of the three references, teach or suggest all of the claim limitations of the present application. None of the references teach a non-aqueous single phase vehicle.

For at least the above reasons Applicants believe that all the currently pending claims are allowable and request the Examiner to reconsider and allow this application. Should any questions arise in connection with this Response, or the application in general, the Examiner is respectfully requested to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

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